PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Scott Smith, Christopher Brian Brodeur**
Application No.:	**10/643527**
Filed:	**August 19, 2003**
For:	**[Improved] Composite Vascular Graft**
Examiner:	**Lindsey Michele Bachman**
Group Art Unit:	**3734**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2Q-14457-US02

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application for which claims 15, 16 and 18-23 are pending in the application and were finally rejected in the office action dated May 26, 2009.

A Notice of Appeal was filed in this case on September 28, 2009. The fees required under §1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account 22-0350 for any other fees which may be due with this appeal.

TABLE OF CONTENTS

Identification Page..... cover page

(i) Real Party in Interest 3

(ii) Related Appeals and Interferences 4

(iii) Status of Claims..... 5

(iv) Status of Amendments 6

(v) Summary of Claimed Subject Matter..... 7

(vi) Grounds of Rejection to be Reviewed on Appeal 9

(vii) Argument

Issue 1:..... 11

(viii) Claims Appendix..... 17

(ix) Related Proceedings Appendix..... 19

(x) Evidence Appendix..... 20

(i) Real Party in Interest

The application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

None.

(iii) Status of Claims

Claims 1-23 have been presented in the application. Claims 1-14 and 17 have been canceled. Claims 15, 16 and 18-23 are pending in the application and have been twice or finally rejected. Claims 15, 16 and 18-23 are being appealed. No amendments were made subsequent to the Final Office Action.

(iv) Status of Amendments

A Notice of Appeal was filed on September 28, 2009. No amendments were made to the claims subsequent to the Final Office Action.

(v) **Summary of Claimed Subject Matter**

A summary of representative independent claims as required by 37 C.F.R. §41.37(c)(1)(v) and any dependent claims argued separately, and a non-limiting listing of locations where support may be found [bracketed citations] referring to the specification by page and line number, and to any drawing, is provided as follows:

Claim 15 recites a method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite [page 4, lines 13-18 and page 5, lines 7-20] including combining a polytetrafluoroethylene tape strip and a distensible support structure to form an assembly strip [FIGS. 2-2B; FIGS. 4-6; page 8, line 14 to page 11, line 19; page 12, lines 6-12] and combining the assembly strip with a substantially continuous inner tubular body support by wrapping said assembly strip about said inner tubular body support in a non-overlapping pattern [FIG. 3 and page 11, lines 11-19], such that the distensible support structure is placed in direct contact with said tubular inner body and the tape strip completely overlies the distensible support structure forming a non-continuous outer tubular body of polytetrafluoroethylene components [Abstract; FIGS. 2A and 2B; FIGS. 4-6; page 4, lines 9-11; page 5, lines 7-20; page 10, lines 14-19; page 11, lines 5-9; page 12, lines 1-12; page 13, lines 1-8] .

Claim 19 recites a method of making an implantable intraluminal stent/graft composite prosthesis [page 4, lines 13-18 and page 5, lines 7-20] including providing a continuous ePTFE tubular inner body, wrapping a stent directly against said continuous ePTFE tubular inner body, in a nonoverlapping relationship [FIGS. 2-2B; FIG. 3; FIG. 4; page 6, lines 5-7; page 8, lines 14-22 and page 9, lines 1-4; and page 11, lines 11-19] and wrapping an ePTFE strip about the tubular inner body and stent, to overly the stent [FIG. 2A and 2B; FIG. 3; FIG. 4; page 10, lines 4-22; page 11, lines 1-22; page 12, lines 1-12].

Claim 20 recites a method of making an implantable intraluminal stent/graft prosthesis including providing an ePTFE strip, having a length greater than its width [FIG. 2A; page 5, lines 7-13; page 10, lines 21-22 and page 11, lines 1-3], providing an unwrapped stent, assembling the stent with the strip to make an assembly strip with a stent side and an ePTFE strip side [[FIGS. 2-2B; FIG. 3; FIG. 4; page 6, lines 5-7; page 8, lines 14-22 and page 9, lines 1-4; and page 11, lines 11-19], providing a continuous tubular inner body and wrapping the assembly strip around the inner body in non-overlapping relationship, such that said stent side is placed directly against said inner body [FIG. 2A; FIG. 3A; page 8, lines 18-22 and page 9, lines 1-4; page 11, lines 1-19].

(vi) Grounds of Rejection to be Reviewed on Appeal

I. Whether the Examiner erred in rejecting claims 15, 16 and 18-23 under 35 U.S.C. §103(a) as being obvious over Golds et al. (US Patent 6,001,125) in view of Banas et al. (6,264,684).

(vii) Argument

A. Brief Summary

I. The Examiner erred in rejecting claims 15, 16 and 18-23 under 35 U.S.C. §103(a) as being obvious over Golds et al. (US Patent 6,001,125) in view of Banas et al. (6,264,684).

B. Detailed Argument

I. Whether the Examiner erred in rejecting claims 15, 16 and 18-23 under 35 U.S.C. §103(a) as being obvious over Golds et al. (US Patent 6,001,125) in view of Banas et al. (6,264,684).

Independent claim 15 of the present application is directed to a method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite wherein a polytetrafluoroethylene (PTFE) tape strip is combined with a distensible support structure to form an assembly strip and the assembly strip is combined with a substantially continuous inner tubular body support by wrapping the assembly strip about the inner tubular body support in a nonoverlapping pattern, *such that the distensible support structure is placed in direct contact with both the tubular inner body and the tape strip completely overlies the distensible support structure forming a non-continuous outer tubular body of polytetrafluoroethylene components.*

Claims 16, 18 and 21-23 depend therefrom.

Independent claim 19 is directed to a method of making an implantable intraluminal stent/graft composite prosthesis including, inter alia, *wrapping a stent directly against a continuous ePTFE tubular inner body, in a non-overlapping relationship and wrapping an ePTFE strip about the tubular inner body and stent, to overly the stent.*

Independent claim 20 is directed to a method of making an implantable intraluminal stent/graft prosthesis including, inter alia, *assembling a stent with a ePTFE strip to make an assembly strip with a stent side and an ePTFE strip side and wrapping the assembly strip around the inner body in non-overlapping relationship, such that the stent side is placed directly against the inner body.*

Thus, in each of Applicants' independent claims, the stent is in direct contact with the

the inner tubular body, and the outer ePTFE strip overlies the stent.

It is asserted in the Final Office Action that:

> Claim 15, 16, 18, 20: Golds'125 teaches a stent/graft that contains a continuous inner tubular body (24) and an outer layer of stent (28 or 36) in direct contact with the tubular inner body and an outer PTFE layer (22). This is shown in Figures 7 and 8. The support structure (28 or 36) is in direct contact with the inner tubular layer (see Figure 8). Golds'125 does not teach the formation of an assembly strip made of the stent and an outer PTFE layer.
>
> Banas'684 teaches that it is known to create an assembly strip formed of a non-continuous PTFE tubular outer body (the outer portion of cladding 11) and a distensible support structure (14) that is non-continuously wound around a substantially continuous PTFE tubular inner body (12) (see Figure 1 or 4b). It would be obvious to one of ordinary skill in the art to modify the device taught by Golds'125 with an assembly strip, as taught by Banas'684 because the use of the strip allows the user to control the location of the placement of the distensible structure on the inner tubular body, allowing the user more latitude in controlling the amount of flexibility in the graft device.
>
> Final Office Action, page 3

a. No *Prima Facie* Showing of Obviousness

Golds et al. disclose a PTFE vascular prosthesis including first and second ePTFE tubular structures wherein the second ePTFE tubular structure is disposed externally about the first ePTFE tubular structure to define a distinct porosity change between said first and second PTFE tubular structure and a tubular diametrically deformable intermediate layer interposed between said first and second PTFE tubular structure. See Abstract and claim 1.

The intermediate layer may be either a stent or a helical wrap of ePTFE tape:

> As specifically shown in FIGS. 4 and 5, an additional layer 26 may be employed between inner tube 24 and outer tube 22. Layer 26 may include a helical wrap of ePTFE tape 27 placed over inner tube 24. The additional layer 26, however, may also exist as a sheet, film, yarn, monofilament or multi filament wrap, or additional tube. The additional layer 26 may consist of PTFE, FEP, or other suitable polymer composition to obtain the desired performance characteristics…
>
> As shown in FIG. 4, layer 26 is disposed between inner tube 24 and outer tube 22, and functions as an intermediate layer therein between. It is further contemplated that the

> that the additional layer may be employed over outer tube 22, or an additional layer may be used both over outer tube 22 and over inner tube 24.
>
> With further reference to FIGS. 6-8, a further preferred embodiment of the present invention contemplates placing a stent between the inner tube 24 and outer tube 22, instead of intermediate layer 26 (FIG. 4) so as to form a stent/graft composite device 25. Several advantages exist in employing such a stent/graft composite. The stent provides the prosthesis with significant strength, and ensures patency of the vessel. Furthermore, the stent permits endoluminal dilution as it expands radially outward once implanted. Such expansion is usually accomplished by an expandable balloon of a delivery device. Alternatively, the stent may be of the self-expanding type which expands upon implantation. Such a stent may be formed of a temperature sensing expanding metal such as nitinol.
>
> Col. 6, lines 38-57

Thus, either a stent or an ePTFE tape strip are employed, but not both, and in no event do Golds et al. contemplate an intraluminal vascular prosthesis without the use of two concentrically disposed tubular members.

Banas et al. disclose "[s]hape memory alloy and elastically self-expanding endoluminal support structures which are at least partially encapsulated in a substantially monolithic expanded polytetrafluoroethylene ("ePTFE") covering …" Abstract.

Banas et al. disclose self-support, self-expanding stent graft devices having structures disclosed in the Summary of the Invention as follows:

> It is another primary objective of the present invention to provide a stent-graft device which consists generally of tubular member fabricated of a biocompatible polymer selected from the group of microporous expanded polytetrafluoroethylene ("ePTFE"), polyethylene, polyethylene terepthalate, polyurethane and collagen, and at least one winding of a elastically self-expanding wire coupled to either the abluminal or luminal surfaces of the ePTFE tubular member or interdisposed between concentrically positioned ePTFE tubular members.
>
> It is a further objective of the present invention to couple the at least one winding of the elastically self-expanding wire to the ePTFE tubular member by cladding a support wire in a polymeric material which has a melt point less than or equal to that of the ePTFE tubular member and below the A_s temperature of the shape memory alloy metal wire.
>
> Col. 4, lines 24-39

The purpose of the cladding is for promoting adhesion of the self-expanding wire to the ePTFE tubular member. See column 7, lines 38-66. Therefore, the cladding is always on the inner surface of the self-expanding wire which is in contact with the tubular member or it would not be able to promote adhesion between the self-expanding wire and the ePTFE tubular member.

Therefore, the self-expanding wire is never in direct contact with the inner tubular member as recited in all of Applicants' independent 15, 19 and 20.

Also, in each of the embodiments represented in FIG. 4, referred to in the Final Office Action in making the rejection, wherein polytetrafluoroethylene is employed as the adhesive or cladding for the wire stent, a second tubular member is added. Refer to col. 8, lines 54-67 and col. 9, lines 1-46 for the steps of making the stent/graft assembly shown in FIGS. 4A-4C.

FIG. 5, also referred to in the Final Office Action, illustrates only an embodiment of a clad wire stent, not a completed stent/graft assembly as disclosed in Banas et al.

Furthermore, because Golds et al. do not contemplate a stent/graft without both an inner tubular member and an outer tubular member and a stent or helical winding of ePTFE disposed therebetween, combining the clad wire stent of Banas et al., would not lead one of ordinary skill in the art to include both a non-overlapping winding of stent or distensible support structure and a strip of ePTFE overlying the stent as recited in Applicants' independent claims 15, 19 and 20.

At most one might be lead to substitute the polymer clad wire stent of Banas et al. for either the stent or the tape strip of Golds et al., the purpose of the cladding to promote adhesion between the stent and the inner tubular member, but one would not be lead to further discard the outer

discard the outer tubular member of the Golds et al. stent/graft.

Prima facie obviousness requires that the combination of references disclose or suggest all of the elements of the claimed invention. To establish *prima facie* obviousness under 35 U.S.C. §103, "the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination … must … be found in the prior art, and not based on applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2142.

Claims 16, 18 and 21-23 which depend from claim 15 are not obvious over this combination for at least these reasons.

CONCLUSION

Reversal of the rejection of claims 15, 16 and 18-23 under 35 U.S.C. §103(a) as being obvious over Golds et al. ((35 Patent 6,001,125) in view of Banas et al. (6,264,684) is respectfully requested.

Respectfully submitted,

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viii. Claims appendix

Claim 15 A method of providing axial and circumferential compliance to an intraluminal prosthesis stent/graft composite, comprising:

(a) combining a polytetrafluoroethylene tape strip and a distensible support structure to form an assembly strip; and

(b) combining said assembly strip with a substantially continuous inner tubular body support by wrapping said assembly strip about said inner tubular body support in a non- overlapping pattern, such that the distensible support structure is placed in direct contact with said tubular inner body and said tape strip completely overlies the distensible support structure forming a non-continuous outer tubular body of polytetrafluoroethylene components.

Claim 16 The method of claim 15 wherein segments of said assembly strip are wrapped circumferentially about said inner tubular body support, to form a non-continuous outer tubular body of polytetrafluoroethylene components.

Claim 18 The method of claim 15, wherein the assembly strip is wrapped with a plurality of helical turns around the inner tubular body, each helical turn defining one of said polytetrafluoroethylene components.

Claim 19 A method of making an implantable intraluminal stent/graft composite prosthesis comprising:

a) providing a continuous ePTFE tubular inner body;

b) wrapping a stent directly against said continuous ePTFE tubular inner body, in a non-overlapping relationship; and

c) wrapping an ePTFE strip about the tubular inner body and stent, to overly the stent.

Claim 20 A method of making an implantable intraluminal stent/graft prosthesis, comprising:

a) providing an ePTFE strip, having a length greater than its width;

b) providing an unwrapped stent;

c) assembling the stent with the strip to make an assembly strip with a stent side and an ePTFE strip side;

d) providing a continuous tubular inner body; and

e) wrapping the assembly strip around the inner body in non-overlapping relationship, such that said stent side is placed directly against said inner body.

Claim 21 A method of claim 15 wherein said combining step (a) includes:

applying said support structure to one side of said tape strip.

Claim 22 A method of claim 21 wherein said applying step further includes:

positioning said support structure on said one side of said tape strap in a wavelike pattern.

Claim 23 A method of claim 21 wherein said combining step (b) includes:

positioning said one side of said tape strap onto said inner tubular body.

(ix) Related Proceedings Appendix

None

(x) Evidence Appendix

None